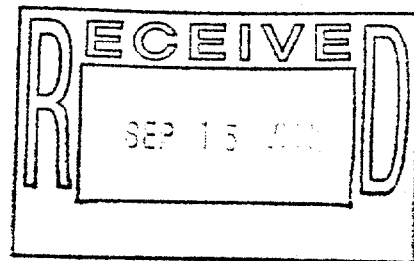


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August 30, 2000



The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Enzymes help sustain life.
- (2) The proteolytic enzymes, for example, work to break down proteins in the digestive tract.
- (3) Promotes healthy digestive function.
- (4) The proteolytic enzymes work in the digestive system and at the cellular level to help digest proteins. Zymex II contains the proteolytic enzymes papain, bromelain, and ficin, that are all found in certain plants and play an important role in digestive system function. In addition to the three proteolytic enzymes, Zymex II also contains amylase – another hydrolytic enzyme that triggers the process of breaking down starch into smaller carbohydrate molecules. Zymex II also contains lipase, an enzyme produced by organs of the digestive system to stimulate the breakdown of lipids.
- (5) Provides alkaline-based digestive support for the acid-sensitive individual.
- (6) Bromelain, papain, and ficin enjoy an optimum pH value of between 6 and 7.5 and remain stable in temperatures of up to 60 and 80°C. These characteristics offer the acid-sensitive individual digestive support without adding acid to the body.

975-0162

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Whole Food Supplements

These statements are made for a dietary supplement containing a proprietary blend of defatted almond (nut), fig (fruit), papain, bromelain, amylase, lipase, and cellulose. Other ingredients include gelatin, water, and natural colors. The name of the product is Zymex® II.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

